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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/931,466
Filing Date: August 16, 2001
Appellant(s): LARRY PASKAR

**MAILED
OCT 30 2007
GROUP 3700**

Gregory E. Upchurch
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 30, 2007, July 12, 2007 appealing from the Office action mailed January 27, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

The examiner notes at the end of the summary of the invention appellant mentions a model and a video tape that was sent to the examiner in the mail. While this model is different from the one the examiner recalls in the personal interview some years ago (see page 9 last paragraph), it may be helpful for the Board's understanding of the invention. While appellant has not included these items in the Evidence section of the brief, the examiner will make these items available upon request from the Board. The examiner can be reached by email or at the phone number listed below.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(8) Evidence Relied Upon

4430083	Ganz et al	2-1984
3,970,089	Saice	7-1976
5,267,982	Sylvanowicz	12-1993
5,401,258	Voda	3-1995
5,195,990	Weldon	3-1993
6723083	Kiemeneij	4-2004
4,580,573	Quinn	4-1986
4,586,491	Carpenter	5-1986
4,474,174	Petruzzi	10-1984
4,659,195	D'Amelio et al.	4-1987
4,617,914	Ueda	10-1986
4,905,667	Foerster et al.	3-1990
4,577,621	Patel	3-1986

US Patent Classification System -Class/subclass 600/148 definition

Takahashi, T. "Atlas of the Human Body"; HarperCollins Publishers, 1994. page 66. Attached to Examiner's Answer

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 22 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 29 recites a method in which the inner surgical element is fixed into two different out of plane shapes for periods of time that permit a medical procedure. The examiner cannot find this sequence of events in the original specification or claims. The examiner cannot find this sequence of events in the original specification or claims. Appellant's specification demonstrates a plurality of shapes that may be formed by manipulating the inner catheter and the outer catheter bodies. In figures 15 and 15a, it is demonstrated that an out of plane shape may be made. However claim 29 goes beyond the mere forming of shapes and has steps that require a time period in which a procedure is performed with two out of plane shapes. The examiner does not find this specific sequence of events but merely finds the formation of different configurations in the specification. Claim 22 has similar limitations concerning reforming the inner element into a second shape after a first out of plane fixation step, and then performing a medical procedure, steps which are not immediately apparent from the original disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ganz et al. USPN 4,430,083. Ganz teaches an outer catheter 57a with an inner surgical element having protruding tip 105 that can be observed in figures 11-13. The inner surgical element is in the form of inner catheter 11a or inner catheter 11b, each have a planar bend 103 and transverse distal tips as shown in figures 6-8. The different catheters include tips 105a and 105b respectively at the end of the inner catheter, which have curved portions that are transverse to the plane of the bend section 103. (column 7 lines 7-10, column 3 lines 15-34). Bend sections 101 and 103 are configured to have the same spacings and angles as the bends 67a and 109 in such a manner that when inserted the sections 101, and 103 find their natural, unstressed planar configuration (column 7 lines 33-37). Therefore outer catheter bend section 67a is also planar with section 103 when the latter is inserted therein with either the tip 105a or 105b protruding out of the plane defined by the bend sections. In this regard the examiner considers the outer catheter 57a with the inner catheter(s) 11a or 11b disposed therein to be a combination catheter. Outer catheter tube has distal end portion 67a preformed so as to

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be fixed in a first curve portion defining a first plane that matches the plane of inner catheter bend 103. The outer catheter is disposed in the body (Column 7 lines 21-22, column 6 lines 6-10) and the inner surgical element having distal end 105 (b) is disposed therein. As the inner catheter is advanced (column 7 lines 23-44) the inner catheter bends 101 and 103 become aligned with outer catheter member curves 109 and 67a as tip 105 (105b) emerges from the tip. Such a process involves the formation of the combination catheter in which the shape of the distal end is disposed substantially out of the first plane. Since the catheter and inner surgical element are already being used medically for a catheterization procedure the limitation of "a period of time sufficient to permit medical use of the catheter tube or the inner medical element" is met. However, the inner catheter, being in the correct orientation may be advanced and "positioned" (claim 20) in to the anterior descending artery for performing an angiograph or infusion treatment procedure (column 8 lines 13-24). Regarding claim 21 and 22, upon completion of the procedure, the combination catheter would be removed from the patient this would entail the reconfiguration of the combination catheter in a catheterization removal medical procedure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 26, 28, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganz et al. USPN 4,430,083 in view of Saice USPN 3,970,089. Applicant differs from Ganz in explicitly stating a fixing step in which the inner surgical element is fixed in an out of plane configuration. Although in all likelihood a fixing step is performed by Ganz for obvious safety reasons as well as need for other equipment such as an infusion injection device to be connected to the catheter requiring inner catheter stability, Ganz et al is silent to such a step. Nevertheless the examiner provides Saice as a secondary reference to show that it was known to provide sealing members within cardiac catheterization sheaths for sealing and immobilizing the inner catheter with respect to the outer sheath (column 3 lines 20-29). Such immobilization thus includes preventing rotation as well as extension of the inner catheter out of the sheath. See column 1 lines 48-54 for the recognized need and benefit for such devices in sheath catheter combinations in 1974, the filing date of Saice. Regarding claim 12, both sheath 57a and inner catheter 11 have preformed curves that are fixed in their distal end portions. Regarding claims 14 and 16, the distal end curve 105 (b) is disposed in the outer sheath during insertion through the sheath and has a step where the inner catheter is extended out the distal end. At that step curves 105 and 67a are adjacent one another and satisfy the conditions set forth in claims 14 and 16. In regard to claims 31 and 32, the insertion of the inner catheter inside the sheath and tracking along the

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sheath lumen rotates the inner catheter in a clockwise direction with respect to the outer sheath. (column 7 lines 35-49).

Claims 19-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sylvanowicz USPN 5,267,982 alone or further in view of Voda USPN 5,401,258. Weldon USPN 5,195,990 and Kiemeneij USPN 6,723,083 cited as evidence to establish inherent properties as well definitions for one of ordinary skill in the art.

Sylvanowicz uses a catheter/sheath system in figures 10 and 11 with a preformed curve providing a fixed outer sheath (52) similar to applicant's teachings on page 9 lines 23-27. The examiner similarly considers the inner sheath 50 to be an inner surgical element. Regarding claim 19, Sylvanowicz teaches a combination catheter in figure 9 with a fixed curve 60 in outer catheter tube 52 and an inner surgical element in the form of an inner catheter 50 which are disposed in the body together (such as in applicant's specification). The fixed curve portion 60 can be altered by removing the inner catheter from the outer catheter to achieve the shape shown in figure 10. The fixed curve portion may also be altered to various shapes by "banking" off different walls while anchoring the catheter in place as applicant himself teaches on page 17 lines 20-23, yet it is still fixed. In this respect Sylvanowicz shows the curve in fixed curve configurations in figures 9-14. The examiner considers the Sylvanowicz catheter's Judkins type curve (60) to provide a fixed curve in a "distal end portion" of the catheter so as to define a plane. Kiemeneij USPN 6,723,083 is cited as evidence that defining such a portion a "distal end portion" is appropriate to one of ordinary skill in the art since

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Kiemeneij, at column 1 lines 62 to column 2 line 5, is but one example of one of skill in the art describing a "distal end portion" of a Judkins type catheter as "consisting of a straight portion extending from the shaft portion and followed by a curved portion for approximately 180° followed by a straight portion forming a small angle with the straight portion extending from the shaft portion, this last straight portion terminating in a tip portion substantially perpendicular thereto". As in applicant's specification, the inner catheter and outer sheath are disposed in the body at the same time thus meeting the disposing steps in the claims. Since the inner catheter is taught to be rotated in going from the left coronary artery to the right, the distal end of the inner catheter will be formed in an out of the plane configuration with the plane defined by the outer sheath, for a sufficient time to perform medical use of the inner catheter, namely a recatheterization of the coronary arteries by rotation. In other words, no fixing step is required in claim 19. Alternatively, as a second interpretation, since the left and the right coronary arteries to which Sylvanowicz accesses with his catheter tip are displaced approximately at 120 degrees apart as seen in Weldon USPN 5,195,990 figure 5 (which is provided as merely secondary evidence of that which is inherent to Sylvanowicz), as inner catheter is inserted during these two intubation periods of the right or left coronary artery ostia, at least one, if not both configurations will result in out of plane configurations during the intubation orientations. Furthermore, the examiner cites Voda as showing a catheter with a planar body and an out of plane tip to demonstrate that it is possible to have a body that orients the catheter body in one plane within the aortic arch and orients the distal tip out of plane to better align the tip with the coronary artery. Such

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configurations are seen in figure 4d and 5d of Voda USPN 5,401,258. If not inherent to Sylvanowicz to have an out of plane configuration due to relative orientations of the right and left coronary ostia, it would have been obvious to orient the outer sheath 52 in one plane well and the distal tip of the inner body element in another, particularly when the right and left coronary arteries of the patient are shifted anteriorly or posteriorly as taught by Voda. A medical procedure, namely and contrast media injection is performed during these intubation periods.

Claims 22, 24, 26, 28, 29, 32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sylvanowicz USPN 5,267,982 (alone or further in view of Voda USPN 5,401,258) and optionally in view of Saice USPN 3,970,089 or Quinn USPN 4,580,573. (Weldon USPN 5,195,990 and Kiemeneij USPN 6,723,083 and Carpenter USPN 4,586,491 cited as evidence to establish inherent properties of the heart, gaskets and definitions recognized by one of ordinary skill).

In regard to claim 22, Sylvanowicz teaches a combination catheter in figures 10 and 11 with an outer catheter tube 52 and an inner surgical element in the form of an inner catheter 50. Sylvanowicz considers the entire catheter body to form a modified Judkins Left Coronary shaped catheter at is "distal end portion. (See newly cited Kiemeneij USPN 6723083 as explained above). The inner catheter is inserted in the outer catheter member and disposed in the body, namely at the aortic arch of the heart. As shown in figure 12, the catheter is shaped to assume a Judkins left catheter shape.

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After using the catheter for a medical procedure such as an angiography procedure, the outer catheter is withdrawn proximally so as to reshape the outer catheter fixedly in a manner to orient its distal end portion 62 towards the right coronary artery 9 (figure 13). This shifting is said to also orient the inner catheter distal portion generally towards the right coronary ostium as it is extended towards the ostium, the inner catheter *is then* rotated to insert the tip into the ostia to perform a second medical procedure (figure 14), including performing a second angiography procedure in the right coronary artery.

The fitting 64 which is described to be a similar fitting as in the early embodiment 30 and thus provides an adjustable constricting force to help seal the inner tube. Such constriction also provides friction as one of ordinary skill in the art would recognize. Applicant's state that the term "fixing" should be given it's ordinary meaning (page 21 line 1 of the brief) and such meaning would include making firm, stable, or stationary and that no other special meaning should be read into the claim. The examiner believes when Sylvanowicz performs his angiography injections the combination catheter would be stable, firm as well as stationary. The examiner would consider it to be dangerous and against all rationale and wisdom for the device in its final configuration orientation prior to injection or during injection to be unstable, loose, and/or otherwise, moveable. In addition to other stabilizing tasks, the examiner considers it to be inherent or obvious to provide enough constricting force upon the gasket member 64 to result in a stable configuration. (Also see newly cited Carpenter USPN 4,586,491 lines 24-31 for explanation as to how gaskets provide stable configurations using friction) Making angiography catheters stable to lessen the recoil effect caused by "jet effect" is a well

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known step as attested to by applicant himself on page 2 of his specification line 3+.

Optional reference Quinn USPN 4,580,573 is provided as an improvement to the Touchy-Borst type valve used by Sylvanowicz wherein aside from sealing against the inner elements that are inserted into the lumen, they also may be "held in place" column 6 line 38 yet "permitting, if desired, axial movement and rotation of said catheter-like object within said elastic segment". The examiner considers this evidence that the Touchy-Borst valve is considered to be a device for holding catheters and the like in place yet allowing desired manipulation type device thus meeting the ordinary and customary meaning of "fixing". In addition is also considered an obvious substitution to used the valve of Quinn in lieu of the Touchy-Borst for the improved holding and sealing disclosed. The examiner also optionally applies Saice, another introducer type gasket for sealing and holding inner catheters when performing radiopaque injection such as the angiography procedure performed in the Sylvanowicz and Quinn references. In Saice it is taught that the bladder, which operates as a gasket, is inflated to one pressure to allow manipulation of the inner catheter relative to the outer sheath and a second pressure once the catheter is in place and dye is to be injected, to immovably fix the inner catheter with respect to the outer catheter (see column 3 lines 24-29). The examiner considers it obvious for to one of ordinary skill in the art to have likewise tightened down the Touhy-Borst adapter of Sylvanowicz to render the inner catheter immobile during radiopaque dye injection or, alternatively, to have substituted the valve and methods of Saice which offers an alternative configuration for performing dye

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injections. Substituting one leakage preventing valve for another would be an obvious modification to those of ordinary skill in the art.

With respect to claims 24, 26, 28 the examiner notes that that no physician would permit the inner tubes and outer tubes to spin freely relative to one another during injection and would thus provide stability of all components involved. The catheter body is typically attached to an angiography injector which holds the catheter in place, i.e. fixes it in place. The gasket member 64 provides friction contributing to the stability. The tubes are remotely controllable to form curves since manipulation at the proximal end by relative sliding and rotation of the tubes with respect to one another results in different curve configurations. Applicant discloses such remote control on page 9, lines 23-27.

Concerning claims 21 and 22, the step of reforming the distal end of the combination catheter would occur during removal of the distal tip of the catheter member from the right ostia after performing the procedure. Alternatively, and in addressing claim 29, it would have been obvious to treat patients with anterior and posterior displaced right and left coronary arteries as seen in Voda, requiring multiple out of plane configurations during dual angiography.

Claims 19-22, 24, 26, 28-29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petruzzi USPN 4,474,174 in view D'Amelio USPN 4,659,195 and of Ueda 4,617,914. US Patent class/subclass 600/148 and Takahashi reference manual cited as evidence.

Petruzzi et al teach an inner surgical element comprising a catheter with a preformed curve 56 along with a surgical instrument disposed therein, and both further disposed in an outer catheter in the form of a duodenoscope. Since the duodenoscope provides a lumen for the introduction of various instruments and fluids, an endoscope is considered to be a "catheter", however, with additional features. Petruzzi teaches the use of two wheel controls 42 and 42' that permit bending of the distal end of the duodenoscope to allow bending to traverse the alimentary tract including the small intestine region. These types of gastroscopes typically provide bending wires that extend from the control wheels to adjacent the distal tip of the catheter body so as to allow the distal tip to be bent as it is steered through the body. Since Petruzzi does not show each and every feature of the duodenoscope such as the optic fiber and the control wires, the examiner cites D'Amelio et al USPN 4,659,195 to provide the visual details of Petruzzi. To have arranged the control wires and the two control wheel elements of Petruzzi in a manner such as those shown in D'Amelio with a multiple plane bending arrangement (figures 5-8 of D'Amelio) would have been conventional. It is noted that the D'Amelio device is also intended for similar medical applications as taught in column 1 lines 5-7, 36-58. The examiner also considers it obvious to include a conventional control wheel braking system as described in Ueda for holding the curve forming wires in bent configurations cites the PTO patent classification system to demonstrate that such devices were so conventional and common to endoscopes that the USPTO has a subclass specific patents claiming improvements thereto. As can be seen in figure 11 of Petruzzi, the endoscope "outer catheter" is used to position catheter

member 56 into the ampulla of Vater, which is an opening located on the rear wall of the duodenum in a highly curved region which tends to curve towards the front of a person near the stomach and back towards the rear as well as to the left side approaching the ileum. This relative location of the ampulla of Vater is shown to some extent by Petruzzi but can better be seen in the three dimensional figure attached to this office action (Takahashi "Atlas of the Human Body"). As a result of the relative positions, it is seen as a requirement that the outer tubular member of Petruzzi must be used to position the endoscope in a left right manner relative to the page while the catheter 56 is bent and or manipulated to guide its tip into the page so as to access the ampulla of Vater. Such a manipulation requires the inner surgical element, tube 56, snare 58, be positioned out of the plane to the bent curved portion of the outer endoscope. It is apparent to those of ordinary skill in the art that such an out of plane configuration would be necessary in order to access the the ampulla of Vater.

In applying the analysis to the claims, with respect to claim 19, Petruzzi et al shows method in which an outer catheter, in the form of an endoscope 40, positioned in a manner such that it curved with the plane defined by the page (see curved portion extending from the exit of the stomach down to the ampulla of Vater), with an inner surgical element tube 56 or element 58 that has been disposed therein and formed in to a shape wherein a distal end of the inner surgical element extends rearwardly into the page to form an out of plane configuration.. While the Petruzzi device is concerned about the stability of the system (column 4 lines 50- 55) he does not teach that the outer catheter bend is "fixed" within the body. Although, it would seem apparent that such

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fixing would be required, the examiner notes that Ueda (column 4 lines 65-68) teach that it is well known to provide a brake device to hold curved shapes in an endoscope member. To have provided a braking system to hold the shape of the Petruzzi endoscope in a fixed configuration as shown in figure 11 of Petruzzi and the inner catheter has an out of plane curve configuration, would have been obvious to prevent accidental removal of the inner surgical device or to prevent damage to the tissue. Such holding elements for fixing curves in endoscopes are so notoriously old and well known in the art, they have their own classification subclass at the USPTO(class 600/148). The method(s) performed in Petruzzi while fixed in the configuration is interpreted as a catheterization procedure and/or an endoscopic procedure (i.e. viewing the ampulla of Vater, or to apply the snare to aid in removing stones. (Claim 20).

In regard to claim 21, after viewing the ampulla of Vater, and extending the inner surgical element towards the orifice, it would have been obvious to use the bending mechanism (92) to reform the device into a tighter curve to access the opening or to reform it to access that various ducts as taught by Petruzzi..

In regard to claim 22, the Petruzzi inner surgical element, catheter 56 and tool 52 are used in a catheterization procedure as well as a cutting procedure to aid in gall stone removal.

Interpreting the claim language of claims 24, 26, 28 applicant recites "proximally fixing" the distal end portion out of the first plane and fixing it against rotation and translation with respect to the outer catheter. According to Webster's dictionary, "proximally" is defined at or near a point of contact. The examiner considers the side

exiting of the inner surgical element, catheter 56 to confine the rotation of the inner element with respect to the outer tube, as argued by applicant, to prohibit and thus fix the inner surgical element in an out of plane configuration against rotation about, and with respect to the outer catheter viewing instrument. When the inner catheter is inserted within the Ampulla of Vater, the catheter would appear to be translationally fixed due to the bending of the catheter against the endoscope body using wedge member 92. Moving the catheter longitudinally would appear to be difficult once the outer endoscope is set in place. The examiner would also consider it obvious to use a fixing device such as a friction seal in port 48 of the endoscope member to prevent accidental rotation and translation of the catheter tool controller 50 that would result the dislodgement of the inner catheter and tool from the accessed. D'Amellio et al teaches such restricting device for allowing gripping and release of extension elements such as inner catheters and tubes to hold them in position when desired. (column 6 lines 32-40).

As applied to claim 32, the inner surgical element 56 of Petruzzi is initially withdrawn inside of endoscope catheter 56 and is extended out from the sideport opening. In doing so the inner catheter resumes it's preformed configuration. The distal tip of the catheter thus rotates with respect to the endoscope body as it is extended and is further rotated by using element 92, see figure 3 with the rotated catheter being shown in the ghost configuration.

Claims 19-22, 24, 26, 28-29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Amelio USPN 4,659,195 in view Ueda 4,617,914 (US

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class/subclass 600/148) and in further view of Forester et al USPN 4,905,667 or Patel USPN 4,577,621. D'Amelio teaches an endoscope with an inner scope that may be used in the body in the lower gastrointestinal tract, D' Amelio teaches a fixing mechanism 38a and 38b that permits the inner scope to be grasped and released to maintain relative positions of the inner and outer members. Otherwise the inner member may spin freely or be longitudinally extended or retracted. D'Amelio does not teach a mechanism for fixing the outer endoscope in a curved configuration however such mechanisms are conventional and considered obvious to include to maintain stability upon bending as evidenced by Ueda and the cited US patent class/subclass 600/148. Thus the combination of D'Amelio and Ueda possess all of the functions recited in the claims. Forester et al teach the implantation of an inner endoscope member within an outer endoscope member and shows the inner positioned in an out of plane configuration for viewing the gall bladder. To have used the D'Amelio device in the Forester procedure and fixed the inner scope in the extended position as taught by D'Amelio would have been obvious. It would have been obvious to have reconfigured and fixed for inspection, the inner scope for viewing each of the various ducts and organs desired to be examined. Similarly, the D'Amelio device is useful as a colonoscope and to have fixed the scope in various configurations in the complicated colon passages in various planes to inspect and treat various lesions such as polyps would have been obvious to one of ordinary skill in the art of colonoscopy's given the suggestion of D'Amelio to use his device in such procedures.

(10) Response to Argument

Firstly, appellant did not heed the examiner's advice in the Notification of Non-Compliant Appeal Brief mailed 1-3-2007 to review 1205.02 of the MPEP to make certain all of the requirements for appeal brief are satisfied. As a result, appellant had to file an a supplemental brief portion of 7-12-2007 to include the Summary of Claimed subject matter section pointing out where in the specification appellant has support for the claim language in the dependent claims. Unfortunately appellant's new section refers to the wrong specification. Appellant submitted two versions of the specification in the initial filing of the application. The Board can find these papers listed as items number 73 and number 83 in the EDAN system. Item number 73 is the original specification of the parent application, item number 83 is an enhanced version to which appellant added several paragraphs that he felt were inherent to the disclosure. Item number 91 in EDAN is a letter from appellant describing the updated, enhanced specification. Presumably appellant wished to have this specification be entered in lieu of the original. It is not understood why appellant's references in the supplemental brief filed on 7-12-2007 references the original specification and not the enhanced version.

Applicant's first argument found on page 15 is whether the examiner has appropriately applied the general concept of inherency. The examiner has provided secondary evidence to support his position wherever applied. Appellant still apparently doesn't understand the distinction between the examiner's denial of entry of figures back in the parent case 07/834,007 which not only showed a specific of plane configurations, but specific relative sizes that required further evidence to show such would have been apparent to one skilled in the art. The examiner still considers the

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figures to have shown new matter and believes he applied the rules appropriately. None of this has any bearing on the issues at hand.

With respect to the applied art, the examiner notes that appellant has abandoned many of his previous positions and the issues seem to reduced down significantly, however the examiner invites the board to review the argument made in the final office action mailed 1-27-2006 as well as the arguments made in the parent file 08/764,745 which was abandoned after examiner's answer. These issue could have been decide quite some time ago.

With respect to the rejection of claims 19-22 as anticipated by Ganz, rather than address the examiner's interpretation of the art as applied in the final rejection, appellant address irrelevant things such as the fact that two inner catheters are used (which is pointed out in the grounds of the rejection by the examiner), that they are not rotatable (the claims do not require such). Apparently appellant has abandoned the argument that Ganz does not show a combination catheter with an inner element distal portion out of plane. Instead appellant now argues that there is no "forming" step". The examiner has pointed out in the grounds of the rejection, column 7 lines 20-44 how the inner catheter out of plane configuration is formed as the tip 105 emerges from the distal end of the outer catheter. Appellant seems to feel that this is not a forming step. The examiner believes that it is. The combination catheter has a planar configuration while the inner catheter is retracted and forms an out of plane configuration when it is fully extended.

With respect to the rejection of claims 19-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sylvanowicz USPN 5,267,982 alone or further in view of Voda USPN 5,401,258. Weldon USPN 5,195,990 and Kiemeneij USPN 6,723,083, appellant has argued that the examiner has improperly applied the concept of inherency stating the examiner has not established such. The examiner has cited three references that establish why the examiner believes he has appropriately established a reasonable interpretation for "distal end portion" based on Kiemeneij and the reasons why an out of plane configuration is necessarily established or obvious by using the references of Voda and Weldon as secondary evidence. The appellant does not address a single one of these references. The examiner believes the examiner should be affirmed based upon the lack of rebuttal to these showings with out further adieu. The examiner also pointed out that despite appellant's arguments that Sylvanowiz cannot be considered to have a curved distal end portion when it has a straight portion at the distal tip, the examiner reminds appellant that his own figure 15a, which is the only figure to show the claimed out of plane configuration, shows a straight portion 35 on the distal end portion of the inner surgical element, which is the same distal end portion the appellant recited in canceled claim 10. In addition, now canceled claims 14 and 15 specifically recited that the curves may be spaced up to 3 times the arc length or radius of the smaller of the two curves. Therefore applicant's arguments regarding the examiner's interpretation of the claim language "distal end portion" as being inconsistent with either those recognized in the art or inconsistent with applicant's specification are

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without merit. This point was raised by the examiner in the non final office action mailed 5-16-2005 and has never been addressed by appellant aside from canceling the claims the examiner relied upon as evidence.

With respect to the rejection of claims 22, 24, 26, 28, 29, 32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sylvanowicz USPN 5,267,982 (alone or further in view of Voda USPN 5,401,258) and optionally in view of Saice USPN 3,970,089 or Quinn USPN 4,580,573. (Weldon USPN 5,195,990 and Kiemeneij USPN 6,723,083 and Carpenter USPN 4,586,491) appellant never addresses the secondary references but merely states that Sylvanowicz does not have the inherent properties. The examiner considers this insufficient.

With respect to the rejection of claims 24, 26, 28, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganz et al. USPN 4,430,083 in view of Saice USPN 3,970,089, the applicant argues that there is no motivation to add the feature to of Saice to the Ganz catheter. The examiner disagrees, the device both are "combination catheters" and are used for infusing liquids with Ganz showing a secure way of doing so with a fixing member.

With respect to the rejection of claims 19-22, 24, 26, 28-29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petruzzi USPN 4,474,174 in view D'Amelio USPN 4,659,195 and of Ueda 4,617,914. US Patent class/subclass 600/148 and Takahashi reference manual cited as evidence, appellant still cannot grasp the concept of two plane motion as proposed by the examiner. The examiner believes the

evidence shown would render it the claim obvious and that the curving of the scope in a plane orthogonal to the viewing element and tool 80 to enter the Ampulla of Vater in both necessary and obvious. The examiner refers the Board to the arguments made in the final rejection dated 1-27-06.

With respect to the rejection of claims 19-22, 24, 26, 28-29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Amelio USPN 4,659,195 in view Ueda 4,617,914 (US class/subclass 600/148) and in further view of Forester et al USPN 4,905,667 or Patel USPN 4,577,621, appellant focuses upon the use of the D'Amelio scope as used in a turbine engine. The device is also used in the human body. The two planar directional movement of the inner scope with the outer body member can accomplish many out of plane configurations. Considering that the pending claim find root in the ability to form various shapes with no specific method of treatment to the body claimed, the examiner considers the methods claimed to be obvious,

With respect to the 112 first paragraph rejection of claims 22 and 29, the examiner is not satisfied with the piecemeal reconstruction of the claimed invention in appellants comments. Although several out of plane configurations are shown, appellant never describes a reconfiguration being used for two medical procedures with out of plane configurations.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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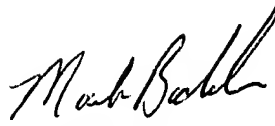
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Mark Bockelman

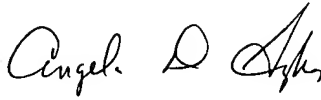
Primary Examiner

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MARK BOCKELMAN
PRIMARY EXAMINER

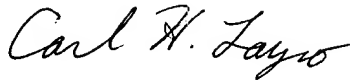
Conferees:

Angela Sykes



SPE Art Unit 3762

Carl Layno

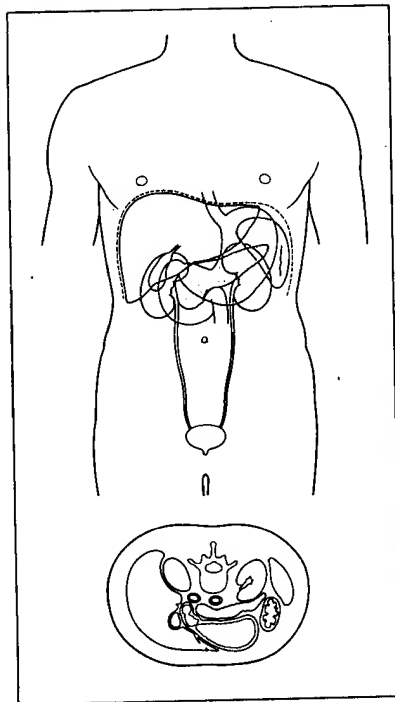


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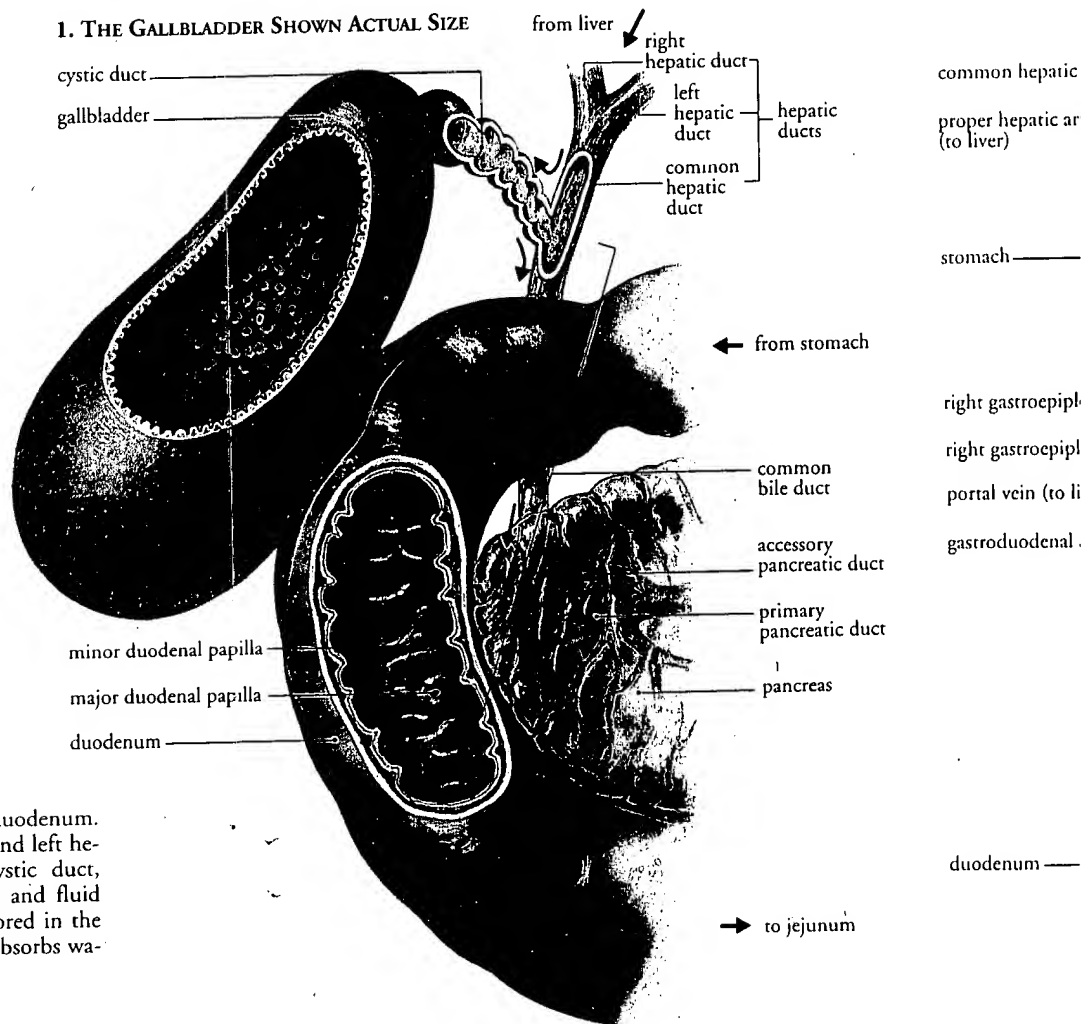
The Gallbladder and Pancreas

•**Gallbladder:** Length: approx 7–9 cm, width: approx 2–3 cm, volume: approx 30–50 ml

•**Pancreas:** Length: approx 15 cm, thickness of the head section: approx 3 cm, weight: approx 70–100 g



1. THE GALLBLADDER SHOWN ACTUAL SIZE



The biliary tract connects the liver and duodenum. It is made up of the hepatic ducts (right and left hepatic ducts, common hepatic duct), cystic duct, common bile duct, and gallbladder. Bile and fluid released from the liver are temporarily stored in the gallbladder, which also adds mucus, and absorbs water and salts to concentrate the bile.

GALLBLADDER

The gallbladder is a small organ located below the liver. It concentrates and stores bile that is produced in the liver.

Location. The gallbladder is attached to a cavity (gallbladder fossa) in the lower section of the liver. From the ventral side a small portion of its tail section is in view.

Shape and Size. Shaped like a pear, the gallbladder is approx 7–9 cm in length, 2–3 cm in width, with a volume of approx 30–50 ml.

Structure. The wall of the gallbladder is composed of mucous membrane packed with numerous folds (mucosal folds), a smooth muscle layer, and a serous covering. It is thin, flexible, and able to stretch considerably. The neck of the gallbladder is attached to the cystic duct, which joins with the hepatic duct from the liver to become the common bile duct that opens into the duodenum.

Function. Approximately half the bile released by the liver is stored in the gallbladder. The bile is then concentrated 1/5 to 1/10 by absorption of water and sodium, mucus is added, and it is combined with food and passed into the duodenum. If food high in fat content is present, amino acids and fatty acids stimulate the duodenum and jejunum to secrete the hormone cholecystokinin. This hormone causes the smooth muscles of the gallbladder to contract and excrete additional bile, which aids in the digestion of fatty materials.

digestive enzymes. It also secretes insulin and glucagon, which regulate the amount of glucose in blood.

Location. The pancreas is located posterior to the stomach and behind the peritoneum on the ventral side of the first and second lumbar vertebrae. The head section of the pancreas is embraced by the curve of the C-shaped duodenum.

Shape and Size. The pancreas is flat and thin and shaped like a comma. It is thickest (approx 3 cm) and widest at the head section, weighs approx 70–100 g, and is approx 15 cm in length. It is light red and white in color and elastic like rubber.

Structure. The exocrine cells of the pancreas produce pancreatic juice and excrete it to the duodenum. The endocrine cells secrete the hormones insulin (from beta cells) and glucagon (from alpha cells) into the bloodstream. The endocrine cells are distributed like round islands within the exocrine cells and are called pancreatic islets, or islets of Langerhans.

Function. Pancreatic juice includes enzymes that digest protein, fat, and carbohydrates (starch). When the contents of the stomach enter the duodenum, digestive hormones are released from the mucous membrane of the duodenum, stimulating synthesis of digestive enzymes and secretion of pancreatic juice. Insulin promotes use of glucose by the muscles and other tissue lowering blood sugar level. Glucagon promotes breakdown of glycogen in the pancreas, raising blood sugar level.

Major Disorders: cholecystitis (inflammation of the gallbladder), cancer of the gallbladder, gallstones, pancreatitis, pancreatic